

R E M A R K S

Applicants do not cancel, add or amend any claims. At this time, claims 124-130 and 143 remain under examination. Applicants provide the declaration of Dr. Muratoglu. Applicants also wish to again thank the examiner for the interview held on August 11, 2003. The office action is discussed below.

The captioned application is entitled to the benefit of priority

On page 2 of the office action, the examiner again denied applicants the right to priority to U.S. application serial no. 08/600,744 on the grounds that the '744 application and the captioned application were "different." Applicants respectfully traverse this determination.

Requirements of priority under U.S. law are set in 35 USC § 120. Section 120 allows priority where claims find support in a previous application that satisfies the first paragraph of 35 USC § 112. As explained in MPEP § 201.11 at 200-63 to 65 (Rev. 1, Feb. 2003), there are six conditions that must be met in order to claim priority, which are as follows:

- A. Support in the parent applications as required by 35 USC §§ 112, 120;
- B. Copendency;
- C. A reference in the specification to the previous applications:

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- E. Claim for priority must be made within a certain time period; and
- F. An English translation of non-English language priority documents.

Applicants believe that the only requirement that the examiner questions compliance is condition A, which deals with the first paragraph of 35 USC § 112. The first paragraph of Section 112 contains the (i) written description, (ii) enablement and (iii) best mode requirements. The examiner appears to have denied priority on the grounds of lack of enablement. See office action dated April 8, 2003 (Paper No. 16) at page 4.

As previously explained, the captioned application is continuation application of a continuation application of a continuation-in-part application of a continuation-in-part application (U.S. Application Serial No. 08/726,313) of the '744 application. The captioned application also incorporates the entirety of the '744 and '313 applications. The details of the co-pendency chain are set forth in the preliminary amendment of January 19, 2001 and the updated filing receipt, dated July 30, 2001.

Applicants provide herewith the declaration of Dr. Orhun Muratoglu, who is an expert in the field. Dr. Muratoglu has reviewed the '744 and '313 applications, and has determined that these priority applications enable and describe in writing the claims contained in the application. The Muratoglu declaration at paragraph 18 sets support in the '744 and '313 applications for all of the claims. Applicants thus submit that the

The captioned application enables packaging and sterilizing

Turning to specific issues noted by the examiner, applicants first discuss the packaging and sterilizing steps found in claims 124 and 130. This subject is discussed in paragraphs 12-16 of Dr. Muratoglu's declaration. Dr. Muratoglu explains that the captioned application and the priority documents describe non-irradiative approaches, such as heat ethylene oxide and heat (steam) for sterilizing medical implants, and the use of these methodologies signifies the use of air-permeable packaging. The use of air-permeable packaging is disclosed in Lewis, *Medical Device Technology* 16-25 (January/February 1991) (Exhibit 2 of the Muratoglu declaration). Given that these approaches were practiced as early as 1991, the skilled person would not encounter undue experimentation in 1996-97 in practicing packaging and sterilization, and therefore no additional disclosure is needed. As explained by the Federal Circuit, the specification need not teach, and preferably omits, what is well known in the art. See *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986); MPEP § 2164.05(a) (Rev. 1, February 2003). Accordingly, the captioned application and priority applications enable practice of the packaging and sterilization. Applicants therefore request withdrawal of the enablement rejection.

Claim 128 is enabled

The examiner had rejected claim 128 on enablement grounds based upon the

the claim. Dr. Muratoglu addresses claim 128 at paragraphs 4-11 of his declaration. Dr. Muratoglu supervised an experiment where UHMWPE was irradiated at 175°C with 100 kGY with an electron beam under nitrogen to cross-link, and then aged and tested the cross-linked UHMWPE according to the parameters set forth in claim 128. The cross-linked UHMWPE so produced met the characterization parameters set forth in claim 128. See paragraph 11 of the Muratoglu declaration. Thus, a cross-linked UHMWPE produced according to the teachings of the captioned application possesses the characteristics set forth in claim 128, and therefore the skilled person following the teachings would achieve such a cross-linked UHMWPE without the need to undertake undue experimentation. Applicants also reiterate that similar data for (A) oxidation levels is discussed at the paragraph bridging pages 14-15 and Example 11, and (B) swell ratios of less than 5 are disclosed in Tables 14 and 15 on page 55 of the captioned application. In sum, applicants have claimed an embodiment of the invention in the manner permitted by MPEP § 2163.07(a) (Rev. 1, February 2003), and applicants therefore request withdrawal of the enablement rejection.

The Saum '975 patent is not prior art under 102(a) or (e)

The earliest possible prior art date for the Saum '975 patent is October 2, 1996 from U.S. Provisional Serial No. 60/027,354.¹ The examiner applied the Saum '975 patent under 35 USC § 102(a), and the earliest 102(a) date for the Saum '975 patent is January 25, 2000, long after applicants' filing dates. Regardless of the examiner's

under 35 USC § 102(e) because the examiner has not analyzed the chain of priority

reliance on 102(a) rather than 102(e), applicants have demonstrated above that the pending claims are entitled to priority dates of February 13, 1996 and October 2, 1996.

First, applicants submit that they are entitled to the first priority date of February 13, 1996, which is over seven months earlier than the October 2, 1996 filing date of the Saum provisional application. Thus, the Saum '975 patent is not prior art to the instant claims. Second, the Saum '975 application is not prior to applicants' second priority date. Both the Saum provisional application (which the examiner has not demonstrated to be an effective date) and applicants' second priority date fall on the same date, namely October 2, 1996. The requirements of 35 USC § 102(a), (e) require the prior art to be "before" the invention date of the applicant, which at this stage is based upon the application filing date. Here, Saum's October 2, 1996 filing date is not before applicants' February 13, 1996 and October 2, 1996 filing dates. Accordingly, the Saum '975 patent is not prior art.

The examiner is not entitled to use the Saum '975 patent in a rejection

The Saum '975 patent is the target of applicants' request for interference. A target patent can only be used as a reference against the interfering application if the target patent is a reference under (i) 35 USC § 102(b) or (ii) 35 USC § 102(e) when an applicant has not made a showing as required by 37 CFR § 1.608. See MPEP § 2306 at page 2300-12, column 1 (August 2001). A rejection applying the Saum '975 patent

claimed by the '975 patent, and thus has not demonstrated that the '975 patent is entitled to its priority date. See MPEP § 2136 (Rev. 1, February 2003).

The Saum '975 patent is not a reference under 35 USC § 102(b) or (e), and applicants have made the requisite showing under 37 CFR § 1.608(a). Accordingly, the rejection should be withdrawn, and the examiner should take the required steps to propose an interference in accordance with MPEP § 2306.01 (August 2001). In the instant situation, only the Patent Office Board of Appeals and Interferences has the jurisdiction to decide patentability to Saum *et al.* or applicants.

Request

Applicants submit that the claims are allowable, and respectfully request an indication to that effect. Applicants further request the application be placed in interference with the Saum '975 patent. The examiner is invited to contact the undersigned at (202) 912-2000 should there be any questions.

Respectfully submitted,



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